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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,950	12/30/2004	Rainer Hipfel	P67772US1	3111

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JACOBSON HOLMAN PLLC
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WASHINGTON, DC 20004

EXAMINER

CHERNYSHEV, OLGA N

ART UNIT	PAPER NUMBER
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1649

MAIL DATE	DELIVERY MODE
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11/30/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/509,950	Applicant(s) HIPFEL ET AL.	
	Examiner Olga N. Chernyshev	Art Unit 1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-15, 17- 26 and 30-31 is/are pending in the application.
- 4a) Of the above claim(s) 11,12 and 21-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-15,17-20,30 and 31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>9/25/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Claims 13-15, 17-20 and 30-31 have been amended and claims 1-10 and 27-28 have been cancelled as requested in the amendment filed on September 25, 2007. Following the amendment, claims 11-15, 17-26 and 30-31 are pending in the instant application.
2. Claims 11, 12 and 21-26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in Paper filed on June 16, 2006.
3. Claims 13-15, 17-20 and 30-31 are under examination in the instant office action.
4. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.
5. Applicant's arguments filed on September 25, 2007 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 13-15, 17-20 and 30-31 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement for reasons of record in sections 8-9 of Paper mailed on June 25, 2007.

Applicant traverses the rejection on premises that the enablement under §112, first paragraph, is satisfied by amending the claims to be limited to “sample” taken from the “temporal cortex, frontal cortex, and/or hippocampus” areas of the brain (p. 10 of the Response). This argument has been fully considered but is not persuasive for the following reasons.

As fully explained in the previous office action of record, the instant invention is based on discovery that human TARPP (hTARPP) mRNA was found to be differentially expressed in specific parts of post-mortem brains of patients with Alzheimer’s disease as compared to control healthy individuals (p. 5 of the instant specification). Specifically, Figures 2 and 3 and Tables 1 and 2 indicate that expression of hTARPP in frontal cortex and temporal cortex and in frontal cortex and hippocampus was higher as compared to the corresponding control ratio values. As such, the utility of the instant claimed hTARPP molecules is established as a marker for Alzheimer’s disease. However, the instant specification fails to provide any other information regarding the instant claimed molecules, such as their physiological role or significance of their enzymatic activity in the etiology of Alzheimer’s pathology of the brain. Therefore, the instant claimed methods are only enabled for diagnosing Alzheimer’s disease by determining the ratio levels of transcriptional product of the gene coding for polypeptide of SEQ ID NO: 1 in samples of brain tissue obtained from the following areas of the brain: temporal cortex, frontal cortex and/or hippocampus, and comparing these levels to the corresponding reference ratio values, wherein the specific results of this comparison as disclosed in the specification stand for diagnosis of AD.

Further, as fully explained earlier, the instant specification is not enabled for “prognosticating Alzheimer’s disease in a subject, or determining whether a subject is at

increased risk of developing said disease” or “for determining activity of a translation or transcription product of the gene coding for hTARPP”. The claims are also not enabled for "monitoring progression of AD", "evaluating a treatment for AD" or determining levels or activity of fragments, derivatives or variants of hTARPP essentially for the same reasons. The instant specification fails to provide any evidence or sound scientific reasoning to support a conclusion that limited data disclosed therein is adequate to provide one skilled in the art with enough guidance to practice the full scope of the claimed methods. Applicant is further advised that the claims, as currently presented, require brain biopsy of a living patient in order to evaluate a treatment of Alzheimer's. While the instant rejection is not based on lack of "the best mode" requirement, the subjection of a patient to brain surgery in order to evaluate risk to develop AD appears to be greater than the development of AD itself.

Since the instant specification does not allow a skilled practitioner to extrapolate the limited results disclosed within the text of the specification to methods beyond the diagnosis of AD, the instant rejection is maintained.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 13-15, 17-20 and 30-31 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Claims 13-15 and 17-20 (and 30-31 as dependent claims) stand vague and ambiguous for recitation of “activity” of hTARPP for reasons of record in section 14 of Paper mailed on June 25, 2007. Applicant argues that activity of hTARPP is interpreted as enzymatic activity (p. 12 of the Response). However, the claims are not limited to activity of the hTARPP polypeptide, but also encompass the activity of the “transcription product” of hTARPP and fragments, derivatives and variants of transcription or translation products, and the specification fails to define metes and bounds of what is recited in the claims.

11. Further, claim 30, as currently amended, does not make sense as reciting samples of temporal cortex “comprising cerebrospinal fluid or blood”. Clarification is required.

Conclusion

12. No claim is allowed.


13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey J. Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Olga N. Chernyshev, Ph.D.
Primary Examiner
Art Unit 1649

November 26, 2007